

battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[55 FR 48443, Nov. 20, 1990, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

**§ 886.5916 Rigid gas permeable contact lens.**

(a) *Identification.* A rigid gas permeable contact lens is a device intended to be worn directly against the cornea of the eye to correct vision conditions. The device is made of various materials, such as cellulose acetate butyrate, polyacrylate-silicone, or silicone elastomers, whose main polymer molecules generally do not absorb or attract water.

(b) *Classification.* (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See § 886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

**§ 886.5918 Rigid gas permeable contact lens care products.**

(a) *Identification.* A rigid gas permeable contact lens care product is a device intended for use in the cleaning, conditioning, rinsing, lubricating/re-wetting, or storing of a rigid gas permeable contact lens. This includes all solutions and tablets used together with rigid gas permeable contact lenses.

(b) *Classification.* Class II (Special Controls) Guidance Document: "Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

[62 FR 30987, June 6, 1997]

**§ 886.5925 Soft (hydrophilic) contact lens.**

(a) *Identification.* A soft (hydrophilic) contact lens is a device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage. The device is made of various polymer materials the main polymer molecules of which absorb or attract a certain volume (percentage) of water.

(b) *Classification.* (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See § 886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

**§ 886.5928 Soft (hydrophilic) contact lens care products.**

(a) *Identification.* A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/re-wetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) *Classification.* Class II (Special Controls) Guidance Document: "Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products."

[62 FR 30988, June 6, 1997]

**§ 886.5933 [Reserved]**

**PART 888—ORTHOPEDIC DEVICES**

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- 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.
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- 888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis.
- 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.
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- 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.
- 888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis.
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- 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
- 888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.
- 888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.
- 888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.
- 888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.
- 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.
- 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.
- 888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.

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- 888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.
- 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
- 888.3720 Toe joint polymer constrained prosthesis.
- 888.3730 Toe joint phalangeal (hemi-toe) polymer prosthesis.
- 888.3750 Wrist joint carpal lunate polymer prosthesis.
- 888.3760 Wrist joint carpal scaphoid polymer prosthesis.
- 888.3770 Wrist joint carpal trapezium polymer prosthesis.
- 888.3780 Wrist joint polymer constrained prosthesis.
- 888.3790 Wrist joint metal constrained cemented prosthesis.
- 888.3800 Wrist joint metal/polymer semi-constrained cemented prosthesis.
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- 888.4150 Calipers for clinical use.
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- 888.4300 Depth gauge for clinical use.
- 888.4540 Orthopedic manual surgical instrument.
- 888.4580 Sonic surgical instrument and accessories/attachments.
- 888.4600 Protractor for clinical use.
- 888.4800 Template for clinical use.
- 888.5850 Nonpowered orthopedic traction apparatus and accessories.
- 888.5890 Noninvasive traction component.
- 888.5940 Cast component.
- 888.5960 Cast removal instrument.
- 888.5980 Manual cast application and removal instrument.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 52 FR 33702, Sept. 4, 1987, unless otherwise noted.

### Subpart A—General Provisions

#### § 888.1 Scope.

(a) This part sets forth the classification of orthopedic devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show

merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an orthopedic device that has two or more types of uses (e.g., used both as a diagnostic device and as a surgical device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 33702, Sept. 4, 1987, as amended at 68 FR 14137, Mar. 24, 2003]

#### § 888.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section